

Food and Drug Administration, HHS

§ 660.25

intended use of the product throughout its dating period. Stability testing shall be performed on an adequate number of representative samples of each group of products manufactured in the same fashion.

(2) Only that material that has been fully processed, thoroughly mixed in a single vessel, and sterile filtered shall constitute a lot.

(3) A lot may be subdivided into clean, sterile vessels. Each subdivision shall constitute a subplot. If lots are to be subdivided, the manufacturer shall include this information in the biologics license application. The manufacturer shall describe the test specifications to verify that each subplot is identical to other sublots of the lot.

(4) Each lot of Blood Grouping Reagent shall be identified by a lot number. Each subplot shall be identified by that lot number to which a distinctive prefix or suffix shall be added. Final container and package labels shall bear the lot number and all distinctive prefixes and suffixes that have been applied to identify the subplot from which filling was accomplished.

(b) *Color coding of reagents.* Blood Grouping Reagents may be colored provided the added colorant does not adversely affect the safety, purity, or potency of the product and the colorant is approved by the Director, Center for Biologics Evaluation and Research (HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

(c) *Final containers and dropper assemblies.* Final containers and dropper pipettes shall be colorless and sufficiently transparent to permit observation of the contents to detect particulate matter or increased turbidity during use.

(d) *Volume of final product.* Each manufacturer shall identify the possible final container volumes in the biologics license application.

(e) *Date of manufacture.* The date of manufacture shall be the date the manufacturer begins the last entire group of potency tests.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0209)

[53 FR 12764, Apr. 19, 1988, as amended at 64 FR 56454, Oct. 20, 1999]

EFFECTIVE DATE NOTE: At 65 FR 77499, Dec. 12, 2000, § 660.21(a)(2) was amended by removing the word “sterile”; and in paragraph (a)(3) by removing the words “clean, sterile vessels. Each subdivision shall constitute a subplot” and adding in its place the word “sublots”, effective June 11, 2001.

§ 660.22 Potency requirements with reference preparations.

(a) *Potency requirements.* Products for which reference Blood Grouping Reagents are available shall have a potency titer value at least equal to that of the reference preparation.

(b) *Reference preparations.* Reference Blood Grouping Reagents shall be obtained from the Center for Biologics Evaluation and Research (HFN-890), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892, and shall be used as described in the accompanying package insert for determining the potency of Blood Grouping Reagents.

(Information collection requirements approved by the Office of Management and Budget under control number 0910-0209)

§ 660.25 Potency tests without reference preparations.

Products for which Reference Blood Grouping Reagents are not available shall be tested for potency by a method approved by the Director, Center for Biologics Evaluation and Research (HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

(a) *Potency requirements.* Blood Grouping Reagents recommended for the test tube methods, including the indirect antiglobulin tests, shall have the following potency titer values, unless other values are approved by the Director, Center for Biologics Evaluation and Research (HFN-830), Food and Drug Administration, 8800 Rockville Pike, Bethesda, MD 20892.

(1) For Anti-K, Anti- \bar{k} , Anti-Jk^a, Anti-Fy^a, Anti-C^w, at least 1+ reaction with a 1:8 dilution of the reagent.

(2) For Anti-S, Anti- \bar{s} , Anti-P₁, Anti-M, Anti-I, Anti-e (saline), Anti- \bar{c} (saline), and Anti-A₁, at least 1+ reaction with a 1:4 dilution of the reagent.

(3) For Anti-U, Anti-Kp^a, Anti-Kp^b, Anti-Js^a, Anti-Js^b, Anti-Fy^b, Anti-N, Anti-Le^a, Anti-Le^b, Anti-Lu^a, Anti-Lu^b, Anti-Di^a, Anti-M^g, Anti-Jk^b, Anti-Co^b,